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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,717	12/21/1999	HUGH L. NARCISO JR.	353532000710	5304

7590 10/19/2004

RICHARD SKULA, ESQ.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08903

EXAMINER	
MULLEN, KRISTEN DROESCH	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/469,717	NARCISO, HUGH L.	
	Examiner	Art Unit	
	Kristen Mullen	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/21/04 (RCE)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-60 and 63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-60 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/21/04 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 49-55, 58-60, and are rejected under 35 U.S.C. 102(e) as being anticipated by Slepian (5,634,946).

Regarding claim 60, Slepian shows a fastener comprising a tubular member made of a deformable material sized and dimensioned for receiving an end portion of a graft lumen, which is transformable upon application of energy between a non-fluent state and a fluent state in which the tubular member is radially expandable (Col. 10, lines 46-Col. 11, line 5, Col. 12, lines 9-12, and 37-45, Col. 13, lines 13-16).

With respect to claims 49-51, Slepian shows that the tubular member is formed of a biocompatible, bioerodable polymeric material (Col. 7, lines 32-44, Col. 8, lines 4-15).

Regarding claim 52, Slepian shows the polymer is either a homopolymer or a copolymer (Col. 7, lines 46-49).

With respect o claim 53, Slepian shows the polymeric material is polycaprolactone (Col. 8, lines 16-46).

Regarding claims 54-55, Slepian shows the tubular member has an adhesive surface (Col. 12, lines 9-12, Col. 12, lines 52-56, Col. 14, lines 40-46)

With respect to claims 58-59, Slepian shows the tubular member is impregnated with anti-platelet, anti-thrombus, anti-inflammatory, and anti-proliferative compounds (Col. 9, lines 25-43).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Nash et al (6,056,762). Slepian is as explained before. Slepian teaches that the initial pre-deployment design and size of the polymer sleeve will be dictated by the specific application based upon the final physical, psychological, and pharmacological properties desired (Col. 12, lines 28-32). Although Slepian does not teach that the tubular member is pre-shaped to have at least a first bend along the length of the member or a portion of the tubular member extends at an angle of between 30° and 90° relative to a longitudinal centerline, attention is directed to Nash et al. which shows an anastomosis system comprising a tubular member (22) with a first bend along the

length of the member (Fig. 3). Nash et al. shows that a portion of the tubular member extends at an angle between 30° and 90° relative to a centerline (Fig. 3, Col. 6, lines 44-47). Nash et al. teaches that the angled configuration facilitates insertion into the target vessel (Col. 6, lines 46-50). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the tubular member of Slepian with a first bend or a portion of the tubular member extending at and angle between 30° and 90° relative to a centerline as Nash et al. teaches in order to facilitate insertion into a target vessel.

6. Claims 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Pathak (5,662,712). Slepian is as explained before. Although Slepian does not teach of including in the tubular member a chromophore or dye, attention is directed to Pathak which teaches of forming polymeric materials that include a chromophore such as a dye or pigment (Col. 2, lines 54-59). Pathak teaches that the chromophore serves to absorb light produced by a light source and convert it to thermal energy that acts to heat the polymer. It would have been obvious to one with ordinary skill in the art at the time the invention was made to include in the tubular member of Slepian a chromophore in the form of a dye, as taught by Pathak in order for the tubular member to be transformable by the application of light energy.

7. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Hubbell (5,410,016). Slepian is as explained before. Although Slepian does not teach that the material is selected from a group consisting of polyethylene-glycol (PEG) base hydrogels, acrylates, and acrylated urethanes, attention is directed to Hubbell which teaches tissue contacting materials formed from of polyethylene-glycol (PEG) base

hydrogels, acrylates, and acrylated urethanes (Col. 5, lines 15-23, and Col. 27, lines 53-55). Hubbell teaches that the acrylates permit rapid polymerization and gelation and can be polymerized by several initiating systems. Hubbell teaches that PEG is hydrophilic and water soluble and has excellent biocompatibility. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to use this group of materials for the device of Slepian since Hubbell teaches that this group of materials are rapidly transformable upon the application of energy between a non-fluent state and a fluent state, are water soluble, and have excellent biocompatibility.

Response to Arguments

8. Applicant's arguments filed 7/21/03 have been fully considered but they are not persuasive.

9. In response to applicant's argument that Slepian does not show a fastener for sealingly joinging a graft lumen to a target vessel in an anastomosis, the examiner points out that Applicant is relying on language that describes the function of the device rather than the actual structure of the device. Slepian shows sealing of a vessel anastomosis during surgery in Col. 12, lines 10-11. The sealing of vessel anastomosei would fasten the two ends of the anastomosis together, and therefore can be described as a fastener. It would be irrelevant whether the two ends of the anastomosis are also stitched together since such stitching would only serve as an additional fastener. The claims do not recite that the tubular member is the sole fastening means.

Conclusion

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the

grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen (formerly Droesch) whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Muller

Angela D. Sykes

kdm

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700